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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,201	12/20/2001	Stephen Quirk	1443.027US1	1416
21186	7590	08/10/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,201

Applicant(s)

QUIRK, STEPHEN

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/03/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed June 3, 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al (US 6,193,953) in view of Steiner et al (US 4,925,673).

Lohrmann et al disclose protein microparticles that can be comprised of chemically synthesized amino acid polymers (col 5, lines 40-57). Lohrmann et al disclose that the microparticles can comprise fluorines or I¹²⁵ (radioisotope)(label) (col 15, lines 1-16). Lohrmann et al also disclose that the microparticles can comprise a targeting moiety such as an antibody linked to the microparticle (col 13, lines 27-29).

Lohrmann et al differ from the instant invention in failing to specifically teach that the protein microparticle is a proteinoid microparticle.

Steiner et al discloses proteinoid microspheres (microparticles). Steiner et al discloses that the proteinoid microspheres are man made condensation polymers produced by random or directed assembly of natural or synthetic amino acids. Steiner et al disclose methods of producing the microspheres by using heat to condense the amino acids (see examples). Steiner et al disclose a mixture of amino acids comprising an acidic amino acid and a basic amino acid (col 5, lines 27-51).

It would have been obvious to one of ordinary skill in the art to synthesize the protein microparticles of Lohrmann et al using condensed amino acids such as taught by Steiner et al because Lohrmann et al specifically teaches that the protein microparticles can be comprised of synthesized amino acid polymers and Steiner et al specifically teaches that proteinoid microspheres are man made condensation polymers produced by random or directed assembly of synthetic amino acids. Therefore, one of ordinary skill in the art would have a reasonable expectation of success to form the protein microspheres of Lohrmann et al by condensing amino acids such as taught by Steiner et al. Therefore, the combination of Lohrmann et al and Steiner et al disclose proteinoid microspheres.

4. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al in view of Steiner et al as applied to claims 1, 2, 5 and 6 above, and further in view of Mathiowitz et al (US 5,271,961).

See above for teachings of Lohrmann et al and Steiner et al.

Lohrmann et al and Steiner et al differ from the instant invention in failing to teach the proteinoid microsphere is formed by thermal condensation of a mixture of amino acids in the presence of a cross linking agent.

Mathiowitz et al disclose protein microspheres that can be modified. Mathiowitz et al disclose that the modification of the protein can be done by cross-linking the protein using agents such as glutataldehyde (col 6, lines 51-62). Mathiowitz et al disclose that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases (col 5, lines 50-56).

It would have been obvious to one of ordinary skill in the art to incorporate cross-linking as taught by Mathiowitz et al into the modified microspheres of Lohrmann et al because Mathiowitz et al shows that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases.

5. Claims 7, 9, 12-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al (US 6,193,953) in view of Steiner et al (US 4,925,673) and further in view of Kayyem et al (US 6,232,295).

See above for the teachings of Lohrmann et al and Steiner et al.

Lohrmann et al and Steiner et al differ from the instant invention in failing to teach the label is linked the proteinoid microsphere.

Kayyem et al disclose polymeric delivery vehicles that are tissue specific used in MRI applications. Kayyem et al disclose that a contrasting agent (label) is attached

(linked) to the polymeric delivery vehicle. Kayyem et al disclose that this provides for a safe and effective means and for improved targeted delivery of contrast agents to specific cells or tissue (col 2-col 4) and allow for medical imaging.

It would have been obvious to one of ordinary skill in the art to incorporate attached labels as taught by Kayyem et al into the modified protein microparticles of Lohrmann et al because Lohrmann et al specifically disclose that their microparticles can be polymeric (col 5) and used in imaging applications. Further, Kayyem et al teaches that this provides for a safe and effective means and for improved targeted delivery of contrast agents to specific cells or tissue (col 2-col 4) and allow for medical imaging. Therefore, one of ordinary skill in the art would have a reasonable expectation to attach labels as taught by Kayyem et al into the modified proteinoid microparticle of Lohrmann et al.

With respect to claims 13-16 as recited in the instant claims. The claims are directed to intended use of the proteinoid microspheres and therefore are not given patentable weight. Further, since the combination of references disclose the claimed invention and the Applicant has not recited any structural differences over the prior art, the prior art is capable of performing the intended use.

6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al, and Steiner et al as applied to claims 1, 2, 5, 6, 7, 9 and 12-18 and 20-22 above, and further in view of Mathiowitz et al (US 5,271,961).

See above for teachings of Lohrmann et al, Steiner et al, and Kayyem et al

Lohrmann et al, Steiner et al, and Kayyem et al differ from the instant invention in failing to teach the proteinoid microsphere is formed by thermal condensation of a mixture of amino acids in the presence of a cross linking agent.

Mathiowitz et al disclose protein microspheres that can be modified. Mathiowitz et al disclose that the modification of the protein can be done by cross-linking the protein using agents such as glutataldehyde (col 6, lines 51-62). Mathiowitz et al disclose that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases (col 5, lines 50-56).

It would have been obvious to one of ordinary skill in the art to incorporate cross-linking as taught by Mathiowitz et al into the modified microspheres of Lohrmann et al because Mathiowitz et al shows that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases.

Response to Arguments

7. Applicant's arguments filed June 3, 2005 have been fully considered but they are not persuasive.

Applicant argues that neither Lohrmann nor Steiner discloses the present labeled proteinoid microspheres. Applicant states that Lohrmann in fact is disclosing "tanning" the microspheres with a metal salt solution rather than labeling the microspheres. Applicant states that the chromium salts employed do not label the micropsheres and are not used for detection of the microspheres. This is not found persuasive because

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Applicant's amendment to the claims to remove a metal as a label has rendered this argument moot. Further, as stated above Lohrmann et al teaches the microsphere can contain a label as recited in the claims (see above 103 rejections). Applicant further argues that Steiner et al does not teach a label. This is not found persuasive because Examiner has not relied upon Steiner for teaching a label but rather has relied upon Steiner for the protein microparticle is a proteinoid microparticle. Therefore, it is the Examiner's position that the combination of Lohrmann et al and Steiner is appropriate and reads on the instantly recited claims.

Applicant's remaining arguments are moot in view of Applicant's amendments to the claims and are moot in view of the new grounds of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Salceda et al (US 6,902,892) disclose different types of labels used in imaging applications and teaches that the label used will be selected in accordance with the imaging modality to be used (col 8).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

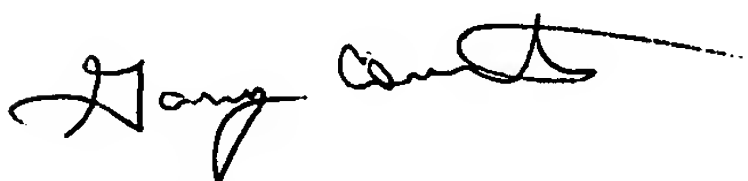
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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